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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,711	04/13/2006	Hiroyuki Ebinuma	289613US0X PCT	3268

22850 7590 11/23/2009  
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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11/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/575,711	<b>Applicant(s)</b> EBINUMA ET AL.	
	<b>Examiner</b> Patricia A. Duffy	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 6, 9, 10 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 13, 15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 10, 14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-8-09 has been entered.

The amendment filed 9-8-09 has been entered into the record. Claims 2-4, 7-8 and 11-12 have been cancelled. Claims 1, 5, 6, 9, 10 and 13-17 are pending. Claims 5, 6, 13, 15 and 17 are withdrawn as drawn to a non-elected invention. Claims 1, 9, 10, 14 and 16 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

***Rejections Withdrawn***

The rejection of claims 1 and 9-10 under 35 U.S.C. 102(b) as being anticipated by Waki et al (The Journal of Biological Chemistry, 278(41):40352-40636, 10 October 2003; of record on 1449) is withdrawn based on the amendment to the claims.

The rejection of claims 1, 3, 4, and 9-12 under 35 U.S.C. 103(a) as being unpatentable over Fruebis et al (PNAS 98(4):2005-2010, Feb 13, 2001; of record) is withdrawn based on the amendment to the claims.

***New Rejections Based on Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it

is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9, 10, 14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants point to paragraphs 13, 14 and 22 of the specification for support for the new limitation of "the acid or salt having a pH of 4 or less" and the original claims. The original claims and paragraphs 13 and 14 do not convey the concept of the acid or salt having a pH of 4 or less. Paragraph 22 recites the following: "The acid or a salt thereof may also be used as a buffer, and in such a case, pH of the buffer is preferably 4 or less." That is the concept is when the acid or salt forms a buffer, the buffer is pH 4 or less. A buffer formed by an acid is exemplified by Waki et al (The Journal of Biological Chemistry, 278(41):40352-40636, 10 October 2003; of record on 1449): 50 mM Tris-HCl pH 6.8. In a buffer of this type, the acid is HCl as contemplated by the specification, but present in the buffer at a pH of 6.8. The pH of any acid or salt depends upon the hydrogen ion concentration of the acid solution. The most concentrated solution of HCl has a pH of about 1. More dilute solutions, having less hydrogen ions would have higher pH's. Therefore, the concept of having and acid or salt thereof having a pH

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of 4 or less is not the same as the acid present in a buffer having a pH of 4 or less.

Consequently, the amendment is deemed new matter.

Claims 1, 9, 10, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are *prima facie* indefinite because only solutions of acids and salts can have specific pH's. pH is a measurement based on the specific hydrogen ion concentration in a solution. A pH is the logarithm of the reciprocal of hydrogen-ion concentration in gram atoms per liter and provides a measure on a scale from 0 to 14 of the acidity or alkalinity of a solution. A salt *per se* cannot have a pH as it is not in solution. As such, the indication that the acid or salt thereof has a specific pH in the claims is inconsistent with the definition of pH and the measurement of such in solutions.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Willner et al (US Patent 4,086,059, issued April 25, 1978).

Willner et al teach a binding assay including radioimmunoassay for thyroid hormones. Willner et al teach that a serum sample (i.e. the instant adiponectin multimer

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containing sample) is adjusted by adding acid to create a low acidic condition to inactivate the binding of the thyroid hormone by serum proteins and the critical amount of acid will be reached when the sample solution pH is about 3 or lower (more acidic) (see column 2, lines 8-32). As such, the method steps of the claims are anticipated and the method is not distinguished from that of the prior art.

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cheng et al (US Patent No. 6,066,505, issued May 23, 2000).

Cheng et al teach methods for pre-treatment of serum (i.e. the instant adiponectin multimer containing sample) prior to a fluorescence polarization immunoassay. Cheng et al teach at Example 4 pretreatment of a serum sample with a diluent comprising 1.25% lithium dodecyl sulfate (i.e. the instant surfactant) and 0.85% naphthalene-1-sulfonic acid (acid with pH 4 or less) and incubation. As such, the method steps of the claims are anticipated and the method is not distinguished from that of the prior art.

### ***Status of Claims***

Claims 1, 9, 10, 14 and 16 stand rejected. Claims 5, 6, 13, 15 and 17 are withdrawn from consideration.

### ***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisors, Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner